

**Section 5: 510(k) Summary**

JAN 6 2006

**Device Information:**

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle. Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Electrosurgical Unit and Accessories
Device Classification & Code:	Class II, GEI (21 CFR 878.4400)
Device Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	Estech Cobra Cardiac Electrosurgical Unit Estech Cobra Cable

**Predicate Device Information:**

Predicate Devices:	Cobra Cardiac Electrosurgical System (K013873)
Predicate Device Manufacturers:	Boston Scientific
Predicate Device Common Name:	Electrosurgical Unit and Accessories
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification & Code:	Class II, GEI

**b. Date Summary Prepared**

28 December 2005

**c. Description of Device**

The Estech Cobra Cardiac Electrosurgical Unit and Estech Cable comprise a system that is identical to the Boston Scientific Cobra Cardiac Electrosurgical System.

Both Systems are comprised of three components: the (radiofrequency) RF Probe, Electrosurgical Unit (ESU) and Instrument (Cobra) Cable. The Cable is an accessory to the ESU. The Estech RF Probes have been the subject of previous premarket notifications.

The ESU is a software controlled high frequency electronic instrument, provided with controls for set temperature, power limit, and number of active electrodes. The ESU delivers 460 kHz of RF energy to selected Probe electrodes. The ESU measures

temperatures from the Probe thermocouples and modulates the RF energy to keep all selected electrodes' temperatures essentially the same; it adjusts the power output to maintain the maximum temperature of all selected electrodes close to the set point. The ESU has readouts for temperature, time of energy delivery, and delivered power. Front panel connectors include connections for the Instrument Cable, and third party dispersive or indifferent (DIP) electrodes.

The Instrument Cable (Cobra Cable) connects the ESU to the RF Probe. It is supplied sterile to the user. The User can resterilize the Cable.

**d. Intended Use**

The Estech Cobra Cardiac Electrosurgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissue. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

**e. Comparison to Predicate Device**

The Estech Cobra Cardiac Electrosurgical Unit is identical in intended use, technology, design, materials, manufacture, and packaging to that of the Boston Scientific Cobra Cardiac Electrosurgical System (K013873). The Instrument/Cobra Cables are accessories to their respective ESU's. They, too, are identical to each other.

Estech concludes that the Estech Cobra Cardiac Electrosurgical Unit is substantially equivalent to the Boston Scientific ESU of the Cobra Cardiac Electrosurgical System.

**f. Summary of Supporting Data**

Supporting data is not necessary to support this submission since the Estech Cobra Cardiac ESU is identical to the predicate device, the Boston Scientific ESU of the Cobra Cardiac Electrosurgical System (K013873).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 6 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Estech, Endoscopic Technologies, Inc.  
% Mr. Craig Coombs  
Coombs Medical Device Consulting  
1193 Sherman Street  
Alameda, California 94501

Re: K053326

Trade/Device Name: Estech Cobra Cardiac Electrosurgical Unit & Cable

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and  
Coagulation device and accessories.

Regulatory Class: II

Product Code: GEI

Dated: November 30, 2005

Received: December 12, 2005

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-410 Division  
D.O.  
f/t:GJM:mxh: 1/3/2006

**Section 4: Indications for Use Statement**

510(k) Number (if known): K053326

Device Name: Estech Cobra Cardiac Electrosurgical Unit; Cobra Cable

**Indications For Use:**

The Estech Cobra Cardiac Electrosurgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissue. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use   X  

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler MD for MXM  
**(Division Sign-Off)**

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**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K053326